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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/716,349

11/17/2003

Ellen L. Berg

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EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT

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1631

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/716,349	<b>Applicant(s)</b> BERG ET AL.	
	<b>Examiner</b> Karlheinz R. Skowronek	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17-23 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17 and 19-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Newly submitted claim 23 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention of claim 23 is distinct from the invention of claims 17-22 because the invention of claim 23 has different steps and produces a material different effect from the invention of claims 17-22. For example the invention of claim 23 uses a multi-parameter pattern recognition algorithm to produce an analyzed biomap relative to a reference, the invention of claim 17 does not include these steps or produce this result. Rather, the invention of claim 17-22 results in a recorded profile of measurements. The invention of claim 23 would require a different search query from the invention of claims 17-22 and therefore presents a search burden.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 23 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Status***

Claims 17-23 are pending.

Claims 1-16 are cancelled.

Claims 18 and 23 stand withdrawn as being directed to a non-elected invention.

Claims 17, and 19-22 are being examined.

***Claim Rejections - 35 USC § 112, Second paragraph***

**Response to Arguments**

Applicant's arguments, see p. 4, filed 23 April 2007, with respect to indefiniteness rejection under 35 USC 1120,2<sup>nd</sup> paragraph have been fully considered and are persuasive. The rejection under 35 USC 1120,2<sup>nd</sup> paragraph of claims 17, and 19-22 has been withdrawn.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

This rejection is reiterated from the previous office action.

Claim 17 and 19-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Friend et al. (US PAT 6,801,859), as evidenced by Cole et al. (US PAT 5,342,777).

Claim 17 is directed to a method of analyzing a candidate compound for a biological activity of interest, comprising contacting a test cell culture with said compound, wherein said culture comprises a plurality of factors in an amount sufficient to induce a plurality of pathways; measuring at least two parameters associated with said plurality of pathways and comparing the measurement of said at least two parameters with the measurement from a control cell culture lacking said compound,

and recording said measurements of said test cell culture and said control cell culture to produce a biological dataset profile, wherein said biological dataset profile is indicative of the pathways that are active in said cell culture.

Friend et al teach a method of analyzing a candidate compound for a biological activity of interest, comprising contacting a test cell culture with said compound (col. 34, line 42-43); measuring at least two parameters associated with said plurality of pathways (col. 39, lines 32-33) and comparing (col. 39, lines 34-35) the measurement of said at least two parameters with the measurement from a control cell culture lacking said compound (col.39, line 31), and recording said measurements of said test cell culture and said control cell culture to produce a biological dataset profile (col. 16, lines 32-35), wherein said biological dataset profile is indicative of the pathways that are active in said cell culture. Friend et al teach the use of human kidney cells to evaluate drugs to generate consensus profiles (col. 10, line 56-59), reading on contacting cultured mammalian cells with a compound.

It is inherent to the culture of mammalian cells to include a plurality of factors that affect a plurality of signaling pathways as evidenced by Cole et al. who demonstrate the culturing of mammalian liver cells in a culture medium having growth promoting amounts of factors such as epidermal growth factor and retinoic acid among others (col. 3, line 13-26).

Regarding claim 19, Friend et al. teach cells derived from multi-cellular high organisms (col. 6, lines 34-35) and cells derived from tissue (col. 44, line 66) reading on primary cells.

Regarding claim 20 and 21, Friend et al. teach the treatment of cells to increase or decrease in pathway activity (col. 52, line 19), which reads on treating with an inhibitor or activator of a pathway.

Regarding claim 22, Friend et al. teach the step of compiling a database of profiles (col. 24, lines 44-46).

### **Response to Arguments**

Applicant's arguments filed 23 April 2007 have been fully considered but they are not persuasive. Applicant argues that the applied prior art does not teach each and every limitation of the instantly claimed invention. Specifically, applicant argues Friend et al. (hereafter "Friend") does not teach mammalian cell culture and the activation of a plurality of signaling pathways induced by factors. This is not persuasive. As a summary, Friend teaches a method evaluating compounds or agents by contacting cell cultures with the agent, measuring a plurality of parameters, and recording the measured parameters to produce profiles. Friend teaches the use of mammalian cell cultures in col. 44, line 39-40 and col. 10 lines 56-59 in the context of cell systems having perturbed biochemical pathways. Since it is inherent in the culture of mammalian cells to include a plurality of factors that affect a plurality of signaling pathways, as evidenced by Cole et al. (as indicated above, in the abstract and col. 1, line 67 to col. 2, line 2, for example), the teaching of mammalian cell culture by Friend also reads on plurality of factors and signaling pathways. Thus, taken as a whole, Friend teaches a method of evaluating an agent or compound by contacting mammalian cells with a

Art Unit: 1631

candidate compound and producing a biological data set profile. The rejection of claims 17 and 19-22 is maintained.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

**Nonstatutory double patenting**

Claims 17 and 19-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,656,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-16 of U.S. Patent No. 6,656,695 are species of claims 17 and 19-22 of the instant application.

***Response to Arguments***

The double patenting rejection will be maintained until it is overcome with a terminal disclaimer.

**Provisional nonstatutory double patenting**

Claims 17 and 19-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 9, 10, 14, 33, 34, and 35 of copending Application No. 10/220,999. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending claims 1, 7, 9, 10, 14, 33, 34, and 35 are directed to identifying a mechanism of action of a biologically active agent on a cell in cell culture are species of claims 17 and 19-21 of the instant claims directed to the analysis of candidate compounds for biological activity of interest.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

The provisional double patenting rejection is being maintained.



***Double Patenting***

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

20 June 2007

/KRS/

Karlheinz R. Skowronek

Assistant Examiner, Art Unit 1631

*John S. Brusca June 20 2007*  
JOHN S. BRUSCA, PH.D.  
PRIMARY EXAMINER